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24

(12) **EUROPEAN PATENT APPLICATION**

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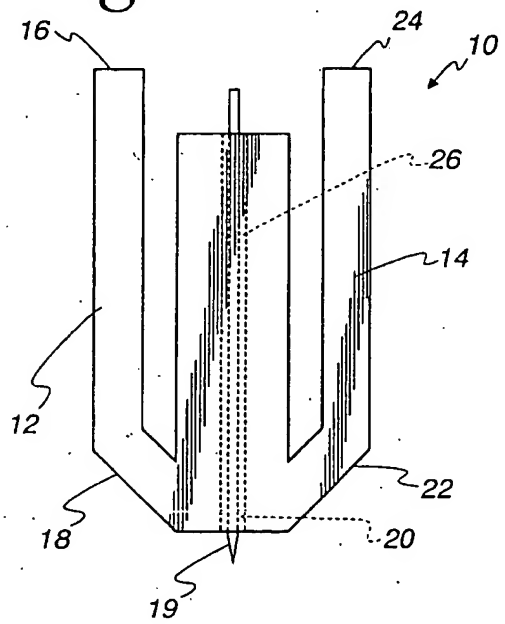
(54) Device for the optical analysis of small sample volumes

(57) An optical waveguiding optical format enables consistent optical analysis of small sample volumes with minimal variation in light path length among optical formats. The optical format is comprised of an input guide, an output guide, and a sample cavity adapted to allow light to pass through a sample on its way from the input guide to the output guide. A lid removed from the light pathway within the format may be provided with a reagent for assisting fluid analysis.

Fig. 1



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Description

FIELD OF THE INVENTION

[0001] The present invention relates generally to medical testing and more specifically to an improved format for optical testing of fluids.

BACKGROUND OF THE INVENTION

[0002] Optical testing of samples has become increasingly popular in recent years due to the speed, accuracy, and efficiency with which test results can be acquired through optical testing. Because of these benefits, optical testing is commonly used in medical applications such as glucose testing. Generally, optical testing in medical applications involves passing light through a sample. In some applications, the sample may be combined with a reagent for testing. Upon passing through the sample or the combined sample and reagent, the test light is altered based on the qualities of the sample or sample/reagent combination. The light which passes through the sample comprises a detection beam which is input into a detector for analysis. Optical testing may employ "formats," objects upon which a sample may be collected and which allow for easy transport and testing of a sample.

[0003] Several problems arise in optical testing applications. One common problem is the contamination of equipment optics when a sample is input for analysis. Such contamination may require error detection for contaminated optics and/or major cleaning procedures for the user, and further results in overall contamination of an analysis instrument. Such contamination may result, for example, from a close proximity of a light source or light detector to the sample application area of a format. Further, in applications using optical formats (i.e., testing formats with optical components through which light travels), the variation of the length of the path through which light travels can lead to variable testing accuracy. Optical formats often incorporate lids that are within the light path, which can add to the variability of light path length. Additionally, when testing particularly small sample volumes, it is desirable to use a short path length and further to eliminate the need for any path length variation technique in the testing instrument. Other problems that arise in the use of formats for optical testing include the need for optimization of reagent deposition into the format and the need for a separate format and a device, such as a needle or lancet, for placing a sample into the format.

[0004] In order to increase the efficiency and accuracy of optical sample testing, it is desirable to reduce or eliminate these known problems.

SUMMARY OF THE INVENTION

[0005] According to one embodiment of the present invention, an optical format isolates source and detection optics from a sample application area using a molded plastic light pipe.

[0006] According to another embodiment of the present invention, an optical format is provided with a light pipe which guides input light through a sample and guides the resulting detection light back toward a detector.

[0007] According to another embodiment of the present invention, an optical format including a light pipe for guiding light through a sample is further provided with a lid at an angle to the sample such that the lid is not within the light path within the sample.

[0008] According to another embodiment of the present invention, a microfabricated optical format is provided with a short path length and allows for minimal path length variation between individual formats.

[0009] According to yet another embodiment of the present invention, a format design including several options for reagent deposition into the format is provided.

[0010] According to still another embodiment of the present invention, an optical format having a wave guide is provided with an integrated lancet needle.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011]

FIG. 1 is a top view of an optical format according to the present invention;
FIG. 2 is a front view of an optical format according to the present invention;
FIG. 3 is a side view of an optical format according to the present invention;
FIG. 4 is an isometric view of an optical format according to the present invention;
FIG. 5 is a top view of an alternative optical format according to the present invention;
FIG. 6 is a cross-sectional view of the section defined by the line 6-6 in FIG. 5;
FIG. 7 is a front view of an alternative optical format according to the present invention;
FIG. 8 is a perspective view of an alternative optical format according to the present invention;
FIG. 9 is a top view of another alternative optical format according to the present invention;
FIG. 10 is a side view of another alternative optical format according to the present invention;
FIG. 11 is a front view of another alternative optical format according to the present invention;
FIG. 12 is a cross-sectional view of the section defined by the line 12-12 in FIG. 11;
FIG. 13 is an isometric view of another alternative optical format according to the present invention;
FIG. 14 is a front view of a sample cavity according to one embodiment of the present invention;
FIG. 15 is a side view of a sample cavity according to one embodiment of the present invention; and

FIG. 16 is an isometric view of a sample cavity according to one embodiment of the present invention.

[0012] While the invention is susceptible to various modifications and alternative forms, specific embodiments are shown by way of example in the drawings and will be described in detail herein. However, it should be understood that the invention is not intended to be limited to the particular forms disclosed. Rather, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

DESCRIPTION OF SPECIFIC EMBODIMENTS

[0013] FIG. 1 shows an optical format 10 according to the present invention. The optical format 10 may be used in the collection and optical testing of samples, for example in medical testing applications such as glucose testing. The optical format 10 may be created using a variety of fabrication techniques, described more fully below, and may be constructed of such materials as polycarbonate, polystyrene or other plastics having the proper optical transmission characteristics.

[0014] An optical format 10 according to the present invention is provided with an input light guide 12 and an output light guide 14. The light guides could alternatively be considered "waveguides" or "light pipes." The input light guide 12 guides light from a light input 16 toward an input reflector 18. The input reflector 18 reflects the light through a sample cavity 20, where the light interacts with a sample or a combination of sample and reagent. For example, reagents that allow glucose measurements may be used. From the sample cavity 20, the light continues toward an output light reflector 22. The output reflector 22 reflects light through the output light guide 14, which guides the light to a light output 24 where it then enters the detection optics in the meter (not shown). According to one embodiment of the present invention, the optical format 10 is further provided with a venting channel 26, which works either with or without a lancet to allow venting or vacuuming of the sample cavity 20. According to one embodiment of the present invention 10, the input reflector 18 and output reflector 22 utilize total internal reflection to guide light respectively toward and away from the sample cavity 20. The surfaces of one or both of the input reflector 18 and output reflector 22 may be provided with reflective coatings.

[0015] The optical format 10 is designed to be mounted in an analyzing instrument (not shown) and aligned with source and detection optics. In the embodiment shown in FIG. 1, the input reflector 18 is disposed at a 45-degree angle to the input light guide 12 and the output reflector 22 is disposed at a 45-degree angle to the output light guide 14, though greater or lesser angles are contemplated depending on the specific application for the format 10. The optical format 10 allows for the isolation of light source optics and light detection optics (not shown) from the sample cavity 20. According to one embodiment of the optical format 10, the input light guide 12 and output light guide 14 are of sufficient length to allow a sample to be kept outside of an instrument for optical measurement of the sample.

[0016] Turning now to FIG. 2, a front view of the optical format 10 is shown, more clearly illustrating the structure of one embodiment of the sample cavity 20. The sample cavity 20 is shown in contact with the venting channel 26. Also visible in FIG. 2 is a full lid 28, which covers one surface of the optical format 10. The full lid 28 is beneficial in applications utilizing a reagent deposited on the lid 28 prior to lamination of the lid to a surface of the optical format 10. Further, it is to be noted that the lid 28 is parallel to the direction of light travel through the sample cavity 20 and does not constitute a portion of the light travel path. Depending on the application, it may be beneficial to provide a lid disposed at alternative angles to the direction of light travel, or covering the sample cavity 20 from different directions.

[0017] As can be seen more clearly in FIG. 3, the sample cavity 20 extends inwardly from a sample-side surface 30 of the optical format 10. FIG. 4 shows an isometric view of the optical format 10, further illustrating the relationships of its individual portions.

[0018] In use, the sample cavity 20 serves as a capillary gap for a cuvette-type cell holding a sample. During sample collection, sample-side surface 30 of the optical format 10 may be placed against the skin, with a lancet 19 placed through the venting channel 26. The lancet 19 may be moved relative to the format 10 in the directions shown by arrow "A" of FIG. 4. The lancet is provided to pierce the skin and further to apply a vacuum to the flesh after lancing. It is to be understood that each embodiment of a format according to the present invention may be provided with or without a lancet depending on particular format applications. The fluid sample is thus drawn or wicked into the sample cavity 20 where it may interact with a reagent provided on the lid 28. Once the sample has been acquired, a light source (not shown) directs light into the light input 16, and a transmission reading is taken at a given wavelength or wavelengths after the light has passed through the sample. These results may be analyzed or converted to a reading corresponding to the amount or concentration of glucose or other analyte of interest, and this reading may be displayed to the user. Following use of an optical format according to the present invention, the optical format may be discarded.

[0019] The present invention allows for several methods of application of a reagent into an optical format. In addition to providing a reagent on the lid 28 before construction of an optical format, other methods of providing a reagent may be used. For example, reagent may be deposited into the sample cavity 20 before the optical format 10 is fully assembled or it may be wicked into the

optical format 10 after the format is assembled and dried.

[0020] Turning now to FIGS. 5-8, an alternative embodiment of an optical format 32 according to the present invention is shown. FIG. 5 is a top view of the optical format 10, and FIG. 6 is a cross-sectional view along the line "6-6" of FIG. 5. FIG. 7 is a front view of the optical format 10 and FIG. 8 is an isometric view of the optical format 10. The primary difference between the optical format 10 of FIGS. 5-8 is the use of a shorter lid 34 and a light transmission segment 36 which extends beyond the dimensions of the input light guide 12 and output light guide 14. This design allows the conservation of materials in the light guide portions as compared to the light transmission segment 36, which may be provided with greater dimensions to accommodate a lancet (not shown), the lid 34, and a reagent (not shown) and further to allow room for sample to be input into the sample cavity 20. In addition, this design reduces the amount of light that is lost when the light passes through the non-sample portion of the transmission segment 36. The lid 34 may be printed with a reagent, or a reagent may be provided on the lid via alternative methods such as screen printing, microdeposition, pin deposition, or as a matrix label containing the reagent.

[0021] Turning now to FIG. 9, an alternative embodiment of an optical format 38 is shown. The optical format 38 of this embodiment is provided without a lid. FIG. 9 shows a top view of an optical format 38 having a sample cavity 40 provided therein. FIG. 10 shows a side view of the optical format 38 and illustrates that the sample cavity 40 is bounded along one side by a cavity base 42. According to one embodiment, the cavity base 42 is integral with the remainder of the optical format 38.

[0022] Turning now to FIG. 11, a front view of the optical format 38 is shown, further illustrating the relationship between the sample cavity 40 and the cavity base 42. FIG. 12 shows a cutaway view along the line "12-12" of FIG. 11 and further shows the dimensions of one embodiment of a sample cavity 40 according to the present invention. According to this embodiment, the cavity base 42 has a length, ℓ_{CB}, of about 0.70 inches, and the sample cavity 40 has a height, h_{SC}, of about 0.035 inches, though it is contemplated that greater or lesser dimensions could be formed based on particular applications.

[0023] FIG. 13 is an isometric view of the optical format 38, more clearly showing the location of the sample cavity 40 in relation to the other portions of the optical format. FIG. 14 is a front view of the sample cavity 40, showing the width, w_{MC}, of a main cavity portion 44 and further showing the width, w_{VC}, of a venting cavity 46. According to one embodiment of the optical format 38, the width, w_{MC}, of the main cavity portion 44 is approximately 0.005 inches and the width, w_{VC}, of the venting cavity 46 is approximately 0.002 inches, though it is to be understood that wider or narrower spacing may be used based on specific applications of the optical format 38. FIGS. 15 and 16, respectively, are a side view and an isometric view of the sample cavity. According to one embodiment, the sample cavity 40 has a depth, d_{sc}, of about 0.035 inches.

[0024] An optical format according to the present invention may be fabricated using a variety of techniques, including microfabrication techniques, which can replicate multiple tool cavities without any significant variations from product to product. One example of a microfabrication technique which may be used to create an optical format according to the present invention is the LIGA process. The LIGA process is named after a German acronym and uses X-ray deep-etch lithography and electroplating and molding to create small formations having significant differences between height and depth measurements, or high "aspect ratios." Utilizing a microfabrication process, path length variation tolerance—that is, the difference in the distance of light travel in different optical formats—can be kept within an acceptable range, even when manufacturing extremely small optical formats. Depending upon the complexity of the format, the range may be within a few microns. Other microfabrication techniques which can be used to manufacture optical formats according to this invention include embossing of plastic sheets or the use of UV cure epoxy over master forms. Further, the capillary gap can be laser cut or molded via conventional molding.

[0025] Using an optical format according to the present invention, it is possible to perform accurate optical sample analysis on sample volumes in the range of from about 200 nl to about 500 nl, though optical formats may be adapted for use with larger or smaller volumes.

[0026] While the present invention has been described with reference to one or more particular embodiments, those skilled in the art will recognize that many changes may be made thereto without departing from the spirit and scope of the present invention. For example, while the present invention has been generally described as directed to medical applications it is to be understood that any optical fluid testing applications might employ the principles of. the invention. Each of these embodiments and obvious variations thereof is contemplated as falling within the spirit and scope of the claimed invention, which is set forth in the following claims.

Claims

1. A format for optical analysis of samples comprising:

   a light input;
   an input light guide in optical communication with said light input;
   an input reflector in optical communication with said input light guide;
   an output reflector in optical communication with said input reflector;

a sample cavity disposed between said input reflector and said output reflector;
an output light guide in optical communication with said output reflector; and
a light output,

wherein said light input, said input light guide, said input reflector, said output reflector, said output light guide, and said light output comprise an approximately planar light transmission path, said format further comprising a lid disposed approximately parallel to said light transmission path.

2. The format of claim 1 further comprising a venting channel connected to said sample cavity.

3. The format of claim 1 wherein said input light guide defines an input light path, and wherein said input reflector is disposed at about a 45-degree angle to said input light path.

4. The format of claim 3 wherein said output light guide defines an output light path, and wherein said output reflector is disposed at about a 45-degree angle to said output light path.

5. The format of claim 1 further comprising a reagent disposed within said sample cavity.

6. The format of claim 5 wherein at least a portion of said lid adjacent said sample cavity is provided with a reagent thereon.

7. The format of claim 1 wherein said format is adapted to be used with a measuring instrument having source optics and wherein said input light guide is of sufficient length to isolate said sample cavity from said source optics.

8. A format for optical analysis of a sample comprising:

an input light guide having an input reflector disposed at one end thereof;
an output light guide having an output reflector disposed at one end thereof; and
a light transmission segment disposed between said input reflector and said output reflector, said light transmission segment so disposed as to allow light to travel through a light transmission path between said input reflector and said output reflector, said light transmission segment further having a sample cavity and a lid, said lid not intersecting said light transmission path.

9. The format of claim 8 wherein said lid has a reagent printed thereon.

10. The format of claim 8 further comprising a vent connected to said sample cavity.

11. The format of claim 8 wherein said input light guide has an input light guide height and said light transmission segment has a light transmission segment height greater than said input light guide height.

12. The format of claim 11 wherein said input light guide has a height of approximately 0.04 inches and said light transmission segment has a height of approximately 0.08 inches.

13. The format of claim 8 wherein said input light guide defines an input light path and said input reflector is disposed at an angle of about 45 degrees from said input light path.

14. The format of claim 8 wherein said output light guide defines an output light path and said output reflector is disposed at an angle of about 45 degrees from said output light path.

15. A method of optically analyzing a fluid comprising:

placing a sample-side surface of an optical format having a sample cavity against a skin surface;
puncturing said skin surface so as to cause sample fluid to gather at said skin surface;
drawing said sample fluid from said skin surface into said optical cavity;
allowing said sample fluid to interact with a reagent provided on a lid adjacent said sample cavity;
directing light through said sample cavity; and
detecting light which has passed through said sample cavity.

16. A format for the optical testing of samples comprising:

an input light path;
an output light path; and
a sample cavity disposed between said input light path and said output light path, said sample cavity having a main cavity portion and a venting cavity connected to said main cavity portion, said main cavity portion having a width of about 0.007 inches.

Fig. 1

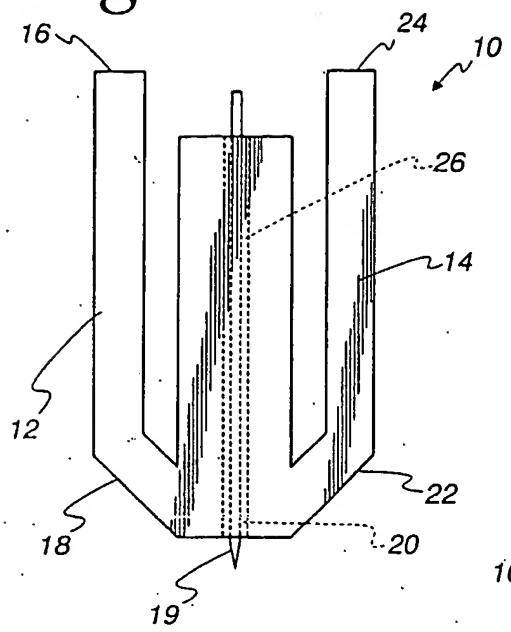


Fig. 2

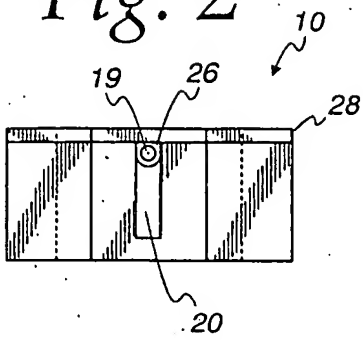


Fig. 3

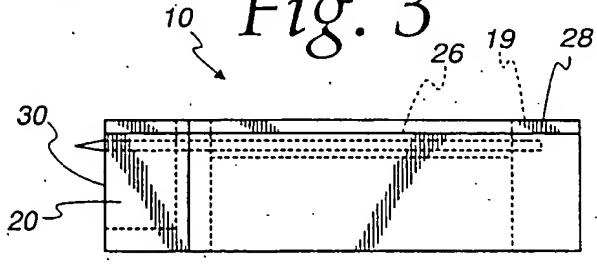


Fig. 4

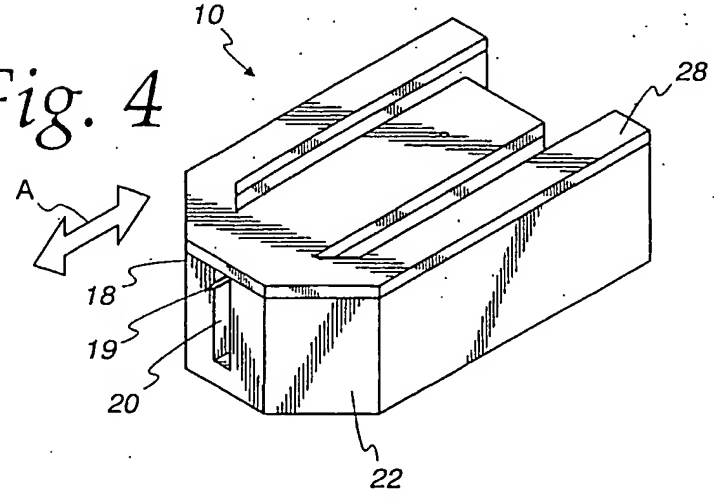


Fig. 5

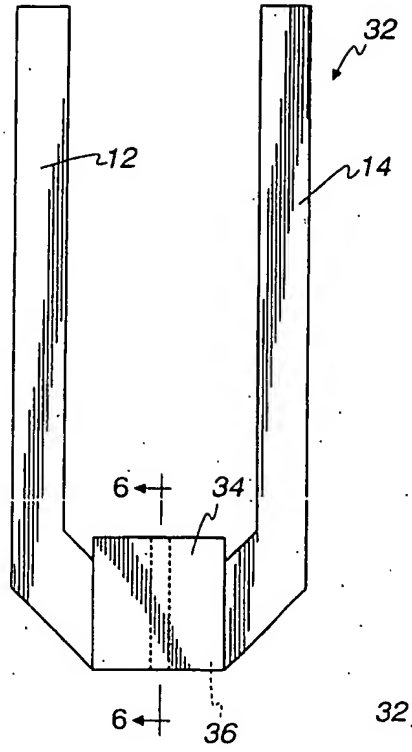


Fig. 6

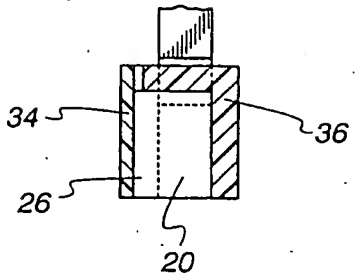


Fig. 7

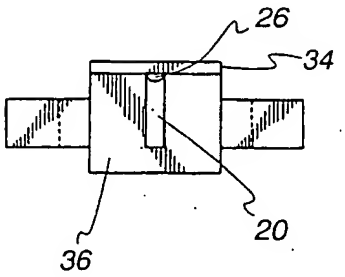


Fig. 8

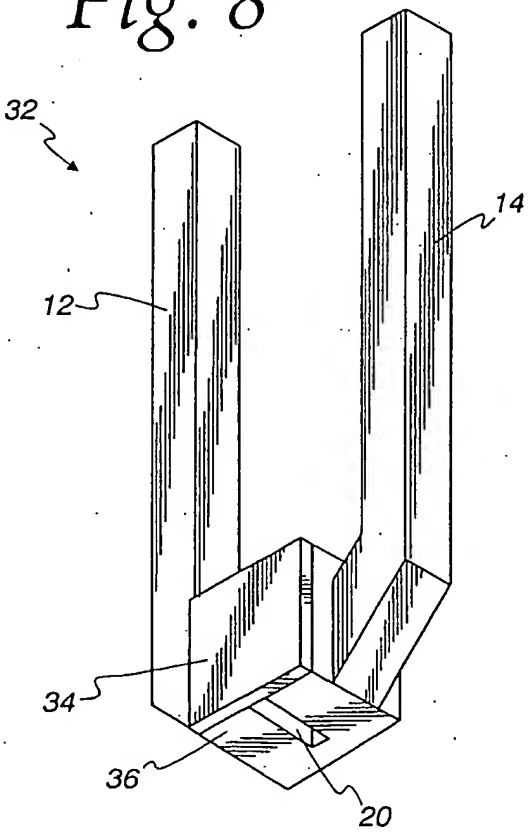


Fig. 9

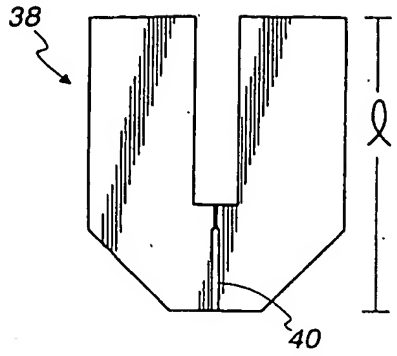


Fig. 10

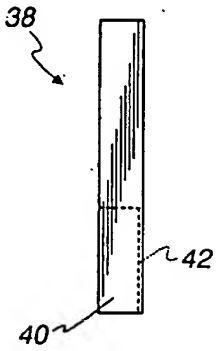


Fig. 11

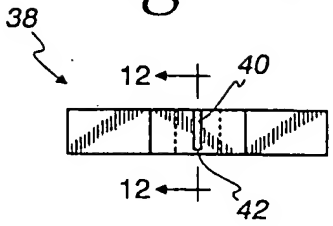


Fig. 12

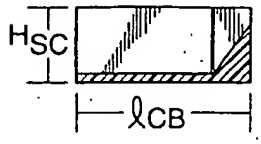


Fig. 13

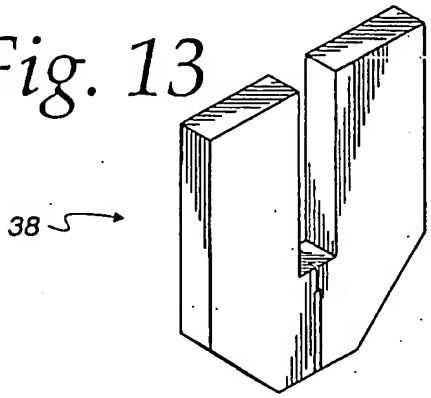


Fig. 14

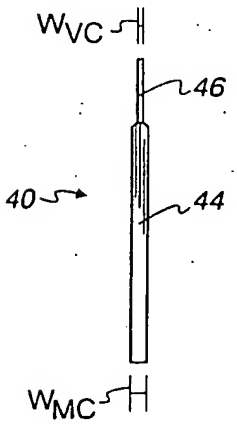


Fig. 15

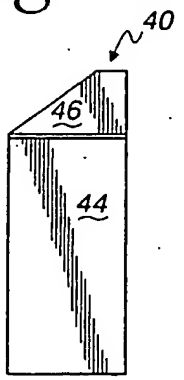
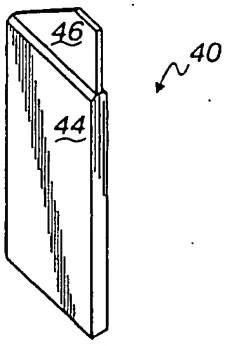


Fig. 16



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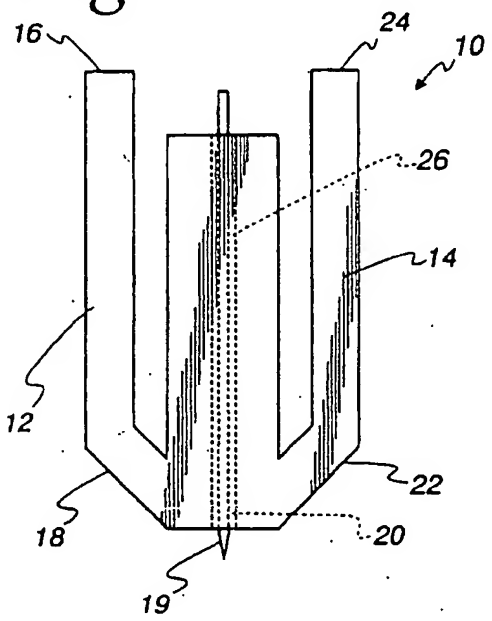
(54) Device for the optical analysis of small sample volumes

(57) An optical waveguiding optical format enables consistent optical analysis of small sample volumes with minimal variation in light path length among optical formats. The optical format is comprised of an input guide (16), an output guide (24), and a sample cavity (20) adapted to allow light to pass through a sample on its way from the input guide to the output guide. A lid removed from the light pathway within the format may be provided with a reagent for assisting fluid analysis.

Fig. 1



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European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number EP 03 02 4613

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	EP 0 254 246 A (PERSONAL DIAGNOSTICS INC) 27 January 1988 (1988-01-27) * column 5, line 22 - line 40 * * column 6, line 39 - line 41 * * column 11, line 24 - line 29 * * column 14, line 32 - line 49 * * figures 5,6,9,20,22 * & EP 0 254 203 A (PERSONAL DIAGNOSTICS INC) 27 January 1988 (1988-01-27)	1-14,16	G01N21/03 A61B5/15 G01N33/49 G01N33/483 G01N21/75
X	WO 88/01376 A (RADIOMETER AS) 25 February 1988 (1988-02-25) * page 11, line 17 - page 12, line 5 * * page 20, line 16 - line 18 * * figure 6 *	1-14,16	

TECHNICAL FIELDS SEARCHED (Int.Cl.7)

G01N
A61B

INCOMPLETE SEARCH

The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.

Claims searched completely :

Claims searched incompletely :

Claims not searched :

Reason for the limitation of the search:

see sheet C

Place of search	Date of completion of the search	Examiner
Berlin	17 November 2004	Navas Montero, E

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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EPO FORM 1503 03.82 (P04C07)

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INCOMPLETE SEARCH SHEET C

Application Number
EP 03 02 4613

Claim(s) searched completely:
1-14 16

Claim(s) not searched:
15

Reason for the limitation of the search (non-patentable invention(s)):

The subject-matter of claim 15 refers to a method of optically analyzing a fluid comprising the step of puncturing the skin surface to cause a sample fluid to gather at said skin surface. A method comprising such a step equals the treatment of the human or animal body by surgery or therapy, as well as is serving to a diagnostic purpose, and is for both reasons excluded from patentability by Article 52(4) EPC. Consequently no search on claim 15 has been carried out.

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 03 02 4613

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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17-11-2004

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82